

D I C K S T E I N S H A P I R O M O R I N & O S H I N S K Y L L P

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June 16, 2004

VIA MESSENGER

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advanced Notice of Proposed Rulemaking – Food Labeling: *Trans* Fatty
Acids in Nutrition Labeling; Consumer Research to Consider Nutrient
Content and Health Claims and Possible Footnote or Disclosure Statements,
Reopening of Comment Period; Docket No. 03N-0076

Dear Sir or Madam:

On behalf of the American Palm Oil Council (“APOC”), we thank FDA for this opportunity to respond to FDA’s advanced notice of proposed rulemaking and reopening of the comment period “Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,” 69 Fed. Reg. 20838 et seq. (April 19, 2004) (“ANPRM”).

Among the issues on which FDA requested comment are: (1) whether there should be a % DV for *trans* fat; (2) whether the % DV for saturated fat and *trans* fat should be listed together or separately on the Nutrition Facts panel; and (3) whether a % DV for *trans* fat would eliminate a need for a footnote about *trans* fat. We submitted comments on these issues in our letter dated April 14, 2004. We write once more to provide FDA with pertinent information from a recent meeting of the Food Advisory Committee Nutrition Subcommittee (“FAC Subcommittee”), which further confirms that FDA should adhere to its original decision against establishing a % DV for *trans* fat, and should require on labels of foods which contain *trans* fats a footnote advising consumers to keep intake of *trans* fats low while maintaining a nutritionally adequate diet.

The FAC Subcommittee is comprised of widely-respected health professionals and scientists. Its mission is to offer the best advice pertaining to nutrition

and to provide advice and recommendations to FDA, based on the opinions of qualified experts in the field. FDA should give great weight to the FAC Subcommittee's findings.¹

A. FDA Should Adhere To Its Decision Against A % DV For *Trans* Fat

In its July 2003 final rule, FDA, after careful consideration, decided against establishing a % DV for *trans* fat. This decision is supported by a majority vote of the FAC Subcommittee that there is insufficient scientific evidence to support establishing a specific % DV for *trans* fat. One participant, Dr. Alice Lichentenstein, Ph.D., a temporary voting member of the subcommittee, noted that establishing a % DV for *trans* fat would imply that there should be a certain minimum level of *trans* fat intake or that *trans* fat is a useful nutrient, and that neither is the case.

In the deliberations of the FAC Subcommittee, it was also noted that a % DV would only serve to confuse consumers by suggesting that a certain % of *trans* fat should be consumed daily. FDA also has concluded, of course, that *trans* fat "in the diet meets no nutritional need."²

B. FDA Should Adhere To Its Decision Against A Combined % DV For Saturated And *Trans* Fat

FDA rejected the adoption of a combined % DV for saturated and *trans* fat, due, in part, to the chemical and physiological differences between saturated and *trans* fat. FDA's decision was supported by the FAC Subcommittee's discussion of a combined % DV and the fact that it did not address a % DV in its recommendations. One FAC Subcommittee member, Dr. Eric Rimm, Ph.D., a temporary voting member of the FAC Subcommittee, noted that

[FDA] decided to separate *trans* and sats on the label and I think they had a good reason. These are different chemicals; they have different biological effects; there are probably a lot of effects related to *trans* that we don't even know yet that probably don't impact [saturated fats].

¹ 21 C.F.R. 14.5; Linda Ann Sherman, *Looking Through a Window of the Food and Drug Administration: FDA's Advisory Committee System*, 2 Preclincia 1, 2 (March/April 2004).

² *Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements*, 69 Fed. Reg. 9559, 9559 (March 12, 2004).

C. FDA Should Require A Footnote Regarding *Trans* Fat Consumption

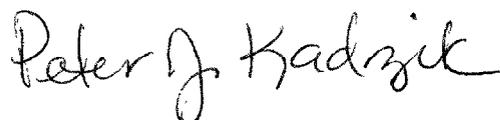
The FAC Subcommittee unanimously concluded, based on their review of scientific studies, that *trans* fats are more adverse than saturated fats, with respect to coronary heart disease. The FAC Subcommittee concluded that *trans* fat is distinct from saturated fat in that it raises levels of LDL cholesterol and does not increase levels of HDL cholesterol. Dr. Rimm noted that intake of *trans* fat "should be as low as possible, especially for children," and that there are "no health reasons to have *trans* in our diet." Dr. Rimm also stated,

[m]y concern is that we need to inform people and educate them, and my concern is that forever people will think that a gram of *trans* fat is the same as a gram of saturated fat and the growing body of evidence would suggest that is not the case, that a gram of *trans* is probably worse than a gram of saturated fat.

These actions by the FAC Subcommittee and statements by its members provide further justification for requiring foods which contain *trans* fat to include a footnote on the Nutrition Facts label stating that, "Intake of *trans* fat should be kept low while maintaining a nutritionally adequate diet." Such a footnote will help establish in the minds of consumers that *trans* fats differ from saturated fats and that *trans* fats are adverse to their health. It will help dispel any misconception that a gram of *trans* fat is the same as a gram of saturated fat.

We would be happy to provide FDA with any further information, or to discuss these matters further.

Sincerely,



Peter J. Kadzik

Charles L. Miller Jr.

Doreen L. Manchester

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Dear Sir or Madam:

Enclosed you will find an original and two copies of a comment being submitted on behalf of the American Palm Oil Council regarding the above-referenced docket. Please date stamp one of the copies and return to our office with the messenger.

If you have any questions, please feel free to contact me at (202) 955-6658. We thank you in advance for the opportunity to address the FDA regarding this important issue.

Sincerely,



Doreen L. Manchester

DLM/lcj
Enclosure